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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,899	11/14/2003	Thomas D. Klingner	400491	9478

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EXAMINER

WEBB, GREGORY E

ART UNIT PAPER NUMBER

1751

DATE MAILED: 06/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/712,899

Applicant(s)

KLINGNER, THOMAS D.

Examiner

Gregory E. Webb

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 January 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

The following is in response to the applicant's response filed 4/7/06.

Response to Arguments

1. Applicant's arguments filed 4/7/06 have been fully considered but they are not persuasive.
2. It is not clear to the examiner how the applicant has narrowed the scope of instant claim 1. The previous claim used the phrase "inhibiting percutaneous absorption." The claim now read "inhibiting absorption into a person's skin."
3. The definition of "percutaneous" is "Passed, done, or effected through the skin." Thus it seems the scope is unchanged.
4. The applicant argues that the mechanism of Peck is different from the instant invention. However, the instant claims do not describe or require any specific mechanism. Instant claim 1 merely requires an inhibition of absorption. Peck specifically teach inhibiting percutaneous absorption as stated in the previous action (see col. 2, lines 17-23).
5. The applicant further states that Peck teaches molecules with a molecular weight less than 350 which are excluded by the instant claims. However the transitional phrase "including" allows for the addition of compounds with a molecular weight less than 350. Should the applicant wish to exclude any additional components the transitional phrase "consisting of" should be used.
6. Concerning claim 14, this method only requires the application of the composition to a substrate. As the prior art teaches application to the skin and as the compositional limitations are

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met such decontamination steps would be inherent. Furthermore as the prior art is also concerned with protecting a persons skin, such variations as application prior to expose or after expose are at the least obvious variations of the prior arts intended use.

7. Concerning the Tipton references, the applicant admits that Tipton teaches a composition which forms an antimicrobial barrier. Thus broadly the Tipton references do teach the blocking of chemicals albeit not all chemicals. The applicant's claims currently do not require all chemicals to be block. Nor do the instant claims require any specific rate of inhibition. Thus the 3-50 micron pore size would at least in part slow the progress of all chemicals as the diffusion is now limited by movement through small pores. As the applicant's claims do not require a specific amount of inhibition such barriers would inherently slow the progress of chemicals into the skin.

8. Concerning the Kilnger reference, the applicant again makes the mistake of claim interpretation by stating that the instant claims exclude composition which contain solvents with a molecular weight less than 350. As stated above the applicant's claim construction does not limit the inclusion of addition compounds.

Claim Rejections - 35 USC § 102

9. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

10. Previous rejections are maintained for those reasons presented in the previous action as well as those arguments presented above.

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Dunn, Richard L. (US5792469).

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Concerning the absorption, Dunn, Richard L. teaches the following:

11. The composition of claim 9, wherein the **absorption** altering agent is selected from the group consisting of propylene glycol, glycerol, urea, diethyl sebecate sodium, lauryl sulfate, sodium lauryl sulfate, sorbitan ethoxylates, oleic acid, pyrrolidone carboxylate esters, N-methylpyrrolidone, N,N-diethyl-m-tolamide, dimethyl sulfoxide, alkyl methyl sulfoxides, and combinations thereof. (*emphasis added*)

Concerning the skin, Dunn, Richard L. teaches the following:

In a preferred version, the film dressing has a two-layered asymmetric pore structure composed of a core portion and a **skin** portion. The **skin** portion has pores with significantly smaller diameters than that of the pores in the core portion. The **skin** portion can be formed on top of the core portion with the core portion in contact with the tissue, or the **skin** portion or layer may be under the core portion and in contact with the tissue. Alternatively, the film dressing can have a homogeneous pore structure with pores evenly distributed throughout the film dressing. (*emphasis added*)

Concerning the solvent system, Dunn, Richard L. teaches the following:

A **mixture of solvents** can be used to increase the coagulation rate of polymers which exhibit a slow coagulation or setting rate. For example, the polymer can be combined with a coagulant-promoting **solvent system** composed of a mixture of a **good solvent** and a poorer solvent or a non-solvent for the polymer component. It is preferred that the solvent mixture contain an effective amount of the two solvents such that the polymer will remain soluble in the mixture but coagulate upon dissipation or diffusion of the solvents into surrounding tissue fluids at the tissue site. (*emphasis added*)

Claim 23 is rejected under 35 U.S.C. 102(b) as being anticipated by Klingner, Thomas D. (US6670313).

Concerning the absorption and the skin, Klingner, Thomas D. teaches the following:

Disrupting the stratum corneum significantly increases the percutaneous **absorption** of chemical exposure, thereby contributing to the development of irritant or allergic dermatitis. Thus, **skin** cleansers incorporating harsh detergents which can damage the **skin** tend to increase the potential for **skin absorption** of chemical exposure. The addition of cosmetic emollients or "moisturizers" to such cleansers can further promote chemical **absorption**. Commonly used additives, such as aloe vera and isopropylmyristate are rapidly absorbed into the stratum corneum. Moreover, these additives have been proven to be effective vehicles to enhance the **absorption** efficacy of lipophilic drugs. D-limonene, widely employed

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in citrus-based **skin** cleansers, has been shown to be among the most effective penetration enhancers for dermal drug delivery. (*emphasis added*)

Concerning the solvent system, Klingner, Thomas D. teaches the following:

7. The **solvent system** of claim 1, wherein the **first solvent** comprises from about 10 weight % to about 90 weight % of the **solvent system** and the **second solvent** comprises from about 10 weight % to about 70 weight % of the **solvent system**. (*emphasis added*)

Conclusion

11. It is again suggested to the applicant to include specific material limitations into their claims so as to distinguish the instant invention from those of the prior art.

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory E. Webb whose telephone number is 571-272-1325. The examiner can normally be reached on 9:00-17:30 (m-f).

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Douglass McGinty can be reached on (571)272-1029. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'Gregory E. Webb', with a stylized, cursive script.

Gregory E. Webb
Primary Examiner
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gew